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10/591,131

09/26/2006

Audrey Royere

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EXAMINER

CRAIGO, WILLIAM A

ART UNIT

PAPER NUMBER

4131

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/591,131 | Applicant(s) ROYERE ET AL. | |
| | Examiner WILLIAM CRAIGO | Art Unit 4131 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>30 august 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) was submitted and filed on 30 August, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the claim is drawn to a method but gives no recitation of positive steps which are required to define a method.

4. Claim 40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. See rejection of claim 39 above. Claim 40 is dependent from claim 39 and contains all of the limitations of claim 39. As such, since claim 39 is rejected 40 is also rejected for the same reason.

5. Claim 25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant application, the claim is directed to a polymer with a molecular weight of from 50 to 500 kDaltons. However, the claim does not

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specify or particularly point out the composition of polymer it is claiming, and it is not clear to one of ordinary skill in the art what the metes and bounds of the claim are.

6. Claims 39-40 provides for the use of the microspheres from claim 21, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7.

Claim 39 and dependent claim 40 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 21-38 rejected under 35 U.S.C. 103(a) as being unpatentable over Bibette, et. al. US5938581 ('581), and further in view of Okada, et. al. US5643607 ('607) and further in view of Lobo, et. al. US5589322 ('322). Claims 39 and 40 are being interpreted here to be methods for administering the active agent to an animal or human. In the absence of a specific condition to be treated, the examiner uses the prior art to render obvious claims 39-40.

11. In a *Graham v. Deere* analysis the scope and contents of the prior art must first be determined. Prior art in this instance would be directed to drug delivery, emulsion science, and art which speaks to the formation of dispersions in an emulsion. Various forms of monodisperse micro- and nanoparticles and their production were known as effective drug delivery systems available for pharmaceutical formulation. Various polymeric compositions of biodegradable and non-biodegradable polymers have been used. General chemistry knowledge and laboratory practices would also fall within the scope of this invention.

12. Claims 21-26 are directed at biodegradable polymers and the choice of solvent to form the emulsion layer. The '581 patent teaches the formation of an emulsion of

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monodisperse droplets formed by a laminar shearing process in a Couette cell. In the instant application the applicant states that FR 2747321, which is the French patent on which the '581 patent is based, discloses the method in the instant case. (pg. 1, paragraph 0010). The process taught speaks directly to an oil-water emulsion and mentions its utility for use in pharmaceutical formulations of monodisperse emulsions containing an active ingredient. The '581 patent also discloses all of the limitations of claims 34 – 38. The reference does not teach the polymers be biodegradable necessarily, however, it does disclose that the method could be used to prepare monodispersed polymeric vectors "...starting with a monodispersed secondary emulsion of polymerizable monomers, resulting from the process of the invention, to initiate the polymerization reaction in situ." (col. 9, line 39) The '581 patent also discloses the use of ethyl acetate as a preferred solvent for the method. The '581 patent also discusses the use of silicone polymers (col. 2, line 41).

13. The '581 patent also speaks to the physical properties of the emulsion in col 3, that the starting primary emulsion be viscoelastic, that the term viscoelastic has the meaning generally attributed to it in the art, and that the viscoelasticity range is dependent upon the modulus of elasticity, G' and the loss modulus G'' . Examiner notes that it further states that the viscolasticity range is defined when G'/G'' is between 0.1 and 10, and that this ratio is the same as that in claim 21 regarding the ratio of the organic to the aqueous phase. The patent fails to disclose how this number is related to the ratio of the viscosity of the organic and aqueous phase, examiner invites applicant to comment on this relationship for the record. The '322 patent which is directed to

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preparing emulsions with very fine monodispersed particles discloses that "...the ratio of the organic phase viscosity to the aqueous gelatin solution viscosity in the absence of the ionic polymer, measured at the temperature of the dispersion forming step, is greater than a value of 2.0,..." (col. 4, line 42); this value falls within the range of claim 21 and therefore shows that the method claimed was already known in the art at the time of application. The '322 patent also discloses "Generally, as the ratio of the organic phase viscosity to the aqueous phase viscosity (at the temperature of homogenization) is decreased, smaller dispersion particle sizes are achieved." (col.2, line 47) This does not specify a lower limit, but it does suggest that non-zero, positive numbers below 2 are also desirable in order to minimize particle size. It also suggests that the instant application offers an optimized process, which, as patent '581 states "Depending on the nature of the phases present and their respective proportion, a person skilled in the art will thus be able to vary one or other of these parameters, possibly both of them, in order to arrive at the desired effective viscoelasticity, *merely using his general knowledge of the art.*" (col. 4, line 5, emphasis added) one of ordinary skill in the art would be able to do without the teachings of the instant application.

14. The '607 patent is directed to the formation and application of monodisperse microspheres made from a variety of biodegradable polymers; it states they can be used for long duration of administration of proteins or peptides or nucleic acids by various methods known in the art for delivery of microspheres. Each polymer has a different rate of breakdown in biological systems and it is the rate of breakdown which principally determines the rate of delivery of the active agent, particularly for poly(d,l-

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lactide-co-glycolide) microspheres. The '607 patent also explicitly mentions mixed and homo polymers of lactic acid (col. 3, line 31), and mixed or homo polymers of DL-lactic acid/glycolic acid (col. 3, line 36). It also discloses that the period of continuous sustained release depends from the molecular weight of the polymer and the composition ratio of lactic acid/glycolic acid. The various biodegradable polymers claimed in the instant application are well known in the art and it would be obvious to one of ordinary skill in polymer science to use any of the polymers in listed in claim 23 if presented with a problem which required a biodegradable polymer. The '607 patent also discloses the application of microspheres to deliver a peptide and discloses the microspheres as a delivery agent applicable to drugs in general, thus rendering claims 39-40 obvious

15. In regards to Claim 25, molecular weight of the polymer is a property which would be inherent to the polymer composition chosen and the desired time of administration and therefore would be obvious to one of ordinary skill in the art. Ethyl acetate is also listed as a useful solvent in col. 4, line 3 of the '607 patent. Claims 27-29 are directed to solubility of active ingredients. Solubility is an inherent property of the active ingredient chosen; the use of microspheres to deliver active agents lipid soluble, water soluble, or in combination is known in the art. The limitations of claims 31, 32 and 33 are all disclosed in the '607 patent at col. 3, line 59 and col. 3 line 14.

16. Conclusion: No claims are allowed. Considering the evidence presented in the application, there is no reason or reasons present which would indicate that, given their broadest reasonable interpretation in light of the specification, any of the claimed

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elements in claims 21-40 would produce an unexpected or unforeseen result over the prior art in light of the claims as a whole and what is disclosed in the instant specification; therefore a rejection under 103(a) in this case is considered proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CRAIGO whose telephone number is (571)270-1347. The examiner can normally be reached on Monday - Friday, 7:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Craigo/
Art Unit 4131

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**